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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,078	03/22/2004	Lakshmi Vijay	U 015092-8	1385

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EXAMINER	
FERNANDEZ, SUSAN EMILY	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,078	VIJAY ET AL.	
	Examiner	Art Unit	
	Susan E. Fernandez	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,17 and 18* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-11,17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed May 2, 2006, has been received and entered.

Claims 12-16 are canceled. Claims 17 and 18 are new. Claims 1-11, 17, and 18 are pending.

New claim 18 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: It is drawn to a method of killing sperm by using a spermicidally effective amount of bivittoside D, whereas the invention elected for examination is drawn to a composition comprising bivittoside D and its use.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 18 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-6 and 18 are withdrawn.

Claims 7-11 and 17 are examined on the merits to the extent they read on the elected subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-11 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuznetsova et al. (Comp. Biochem. Physiol., 1982, 73C(1): 41-43) taken in light of Antonov et al. (Khimiya Prirodnykh Soedinenii, 1986, 3: 379-80 and CAPLUS English abstract).

Kuznetsova et al. discloses glycoside fractions isolated from various sources by aqueous-alcoholic extractions (page 41, first column, "Isolation of glycoside fractions of Holothuria"), thus the glycosides are in their pure form and are alcoholic extracts. Furthermore, bivittosides were obtained from *Bohadschia vitiensis* (page 42, Tables 1 and 2). Note that Antonov et al. discloses that bivittoside D is found in *B. vitiensis* (CAPLUS English abstract), thus the bivittosides obtained from *B. vitiensis* disclosed in Kuznetsova et al. inherently comprise of bivittoside D. The bivittosides from *B. vitiensis*, which are in one of the glycoside fractions studied by Kuznetosova et al., may be in aqueous or aqueous-alcoholic solutions (page 41, second column, first and second paragraphs). Thus, the bivittosides from *B. vitiensis* are in a composition comprising one or more pharmaceutically acceptable additives (water) as required by instant claims 7 and 8.

Although the reference does not specifically teach that the composition is effective as a spermicidal agent, the compositions are the same, thus the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. As pointed out in MPEP §2112, "the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable". Furthermore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Additionally, the references differ from the instant invention in that they do not expressly disclose the concentrations of bivittoside D in aqueous solution as recited in claims 8 and 11 under examination.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have varied the concentration of bivittoside D in aqueous solution to other concentrations, including those recited in instant claims 8 and 11. The selection of specific suitable concentrations in aqueous solution, including those claimed, clearly would have been an obvious matter of optimization on the part of the artisan of ordinary skill, particularly in view of the prior art's disclosure that different concentrations were prepared (page 41, column 2, first paragraph). Thus, the references render obvious claims 8 and 17.

Furthermore, Kuznetsova et al. and Antonov et al. differ from the instant invention in that they do not expressly disclose bivittosides in compositions in all the forms recited in claim 7.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have prepared the bivittosides obtained from *B. vitiensis* in various forms. One of ordinary skill in the art would have been motivated to do this since one of ordinary skill would have expected that the fungicidal activity of the bivittosides of Kuznetsova et al. would have been suitably applied in the form of the claimed cream, jelly, or free-flowing powder since one of ordinary skill would have been motivated to have placed a known fungicide in a topically applicable form.

Applicant's arguments filed May 2, 2006, have been fully considered but they are not persuasive. Applicant asserts that it is unclear how the claims can be anticipatory by a combination of two references. However, M.P.E.P. 2131.01 indicates that a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to show that a characteristic not disclosed in the reference is inherent. See also paragraph III under M.P.E.P. 2131.01, which discusses that the Federal Circuit indeed had deemed this practice acceptable. Antonov et al. discloses that bivittoside D is a bivittoside of *B. vitiensis*, and therefore, the bivittosides of *B. vitiensis* discussed in Kuznetsova et al. includes bivittoside D.

Applicant also asserts that nothing in the prior art would lead one to choose to incorporate bivittoside D into compositions of the type now claimed (cream, jelly, free-flowing powder). However, Kuznetsova et al. indicates that the search for new sources of glycosides in marine invertebrates and further investigation of biomedicinal properties of these compounds is promising (page 41, first paragraph), thus the biomedicinal application of glycosides from marine invertebrates such as *B. vitiensis* is suggested, and this in turn would have led one to choose to incorporate these glycosides in various pharmaceutical forms, such as those recited in

the claims. Moreover, though fungicides are applied in a variety of different ways, it still would have been desirable to have included bivittoside D in a variety of forms in order to target a variety of sites.

Regarding the choice of a bivittoside D concentration, contrary to applicant's arguments, the selection of a suitable concentration would have been an obvious matter of optimization since the artisan would have recognized that the desired effect, antifungal and antibacterial action, would have been dependent on the concentration of bivittoside D.

Finally, though Kuznetsova et al. does not teach that the composition is spermicidal, as pointed out above, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new.

Thus, a holding of obviousness is clearly required.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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sef